Standard Operating Procedure –

Managing Deviations and Revisions to Standard Operating Procedures under the caBIG™ Program

This cover sheet controls the layout and components of the entire document.

Issued Date: September 19, 2005

Effective Date: October 31, 2005

Department Approval:

Sue Dubman

NCICB Applications Director

QA Approval:

Brenda Duggan

Acting NCICB QA Officer

Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	09/1/2005	SOP Working Group	N/A	Initial release.

1. Purpose

This Standard Operating Procedure (SOP) describes the process for handling and documenting any deviations and/or revisions to SOPs.

2. Scope

2.1 **SOP**

2.1.1 This SOP will be used for all SOPs related to clinical trials research covered under the oversight of the caBIG™ Program and sponsored by the National Cancer Institute (NCI).

2.1.2 Deviations from, or revisions to the body of the SOP are covered in the scope of this SOP and will need to be submitted through the SOP Working Group for review and approval.

2.1.3 Any cosmetic changes to the SOP (e.g. inserting site logo, font changes), do not need to be approved by the SOP Working Group.

2.2 **Attachments**

2.2.1 Modifications of any of the documents listed in the Attachment section of an SOP are not covered by this SOP; however, if the business processes at a caBIG™ site (i.e., cancer center) require modifications to be made, the site is responsible for reporting changes or deviations to the SOP Working Group.

2.2.1 Deviations from, or revisions to the body of any documents included in the Attachment section of an SOP, will not be covered under this SOP, however, the caBIG™ cancer center is responsible for reporting changes or deviations to the SOP Working Group.

3. Requirements

3.1 **SOP**

3.1.1 The content of SOPs should be strictly followed; any departure or deviation from the procedure should be documented and brought to the attention of the SOP Working Group.

3.1.2 caBIG™ sites will need to submit a Change Request Form to notify the SOP Working Group of any proposed deviations and/or revisions to the SOP.

3.1.3 caBIG™ sites will be responsible for managing any deviations and/or revisions locally and will be responsible for the appropriate training on the modifications.

3.1.4 A revision to an SOP must be approved by the SOP Working Group and the SOP updated in accordance with the *SOP for Developing and Maintaining Standard Operating Procedures Under the caBIG Program*.

3.1.5 NCICB will maintain records of all change requests and the approval decisions made by the SOP Working Group.

3.2 **Attachments**

3.2.1 caBIG™ sites will need to notify the SOP Working Group of any proposed deviations and/or revisions to the documents in the Attachment section of the SOP.

3.2.2 caBIG™ sites will be responsible for managing any deviations and/or revisions locally and will be responsible for the appropriate training on the modifications.

4. References/Regulations/Guidelines

Section	SOP Number	SOP Title
4.1	N/A	CDISC Glossary
4.2	AD-001	SOP for Develop and Maintain SOPs
4.3	AD-003	SOP for Release and Distribution of SOPs

5. Roles & Responsibilities

Role	Responsibility
SOP Working Group Member	• Prepare Change Request Form. • Obtain approval from senior clinical staff at site. • Present Change Request to SOP Working Group.
NCICB QA Officer	• Review Change Request Form. • Maintain a record of Change Requests, approval dates and versions.
SOP Working Group	• Review and Approve Change Request Forms.
NCICB Applications Director	• Sign-Off of Change Request Form.

6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all research sites conducting clinical trials under the caBIG™ Program and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

Title	Description
1) Procedure Description for Managing Deviations and Revisions to SOPs	This document provides instructions for the preparation of a Change Request Form and it provides step-by-step guidance to ensure that all deviations and/or revisions are prepared, recorded and managed in a consistent manner.
2) Change Request Form	A standardized form to be used for documenting all details regarding a request for deviation and/or revision.
3) Process Flow for Managing Deviations and Revisions to SOPs	This document graphically depicts the work flow activities, by role, that are performed in the process for SOP deviations and revisions.